UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK
BUFFALO DIVISION

UNITED STATES OF AMERICA ex rel. DEBORAH CONRAD, Plaintiff/Relator, v. ROCHESTER REGIONAL HEALTH and UNITED MEMORIAL MEDICAL CENTER, Defendants.	Case No. 1:23-cv-00438-JLS

DEFENDANTS ROCHESTER REGIONAL HEALTH AND UNITED MEMORIAL MEDICAL CENTER'S REPLY IN FURTHER SUPPORT OF MOTION TO DISMISS

Rochester Regional Health ("RRH") and United Memorial Medical Center ("UMMC") (collectively, "RRH") respectfully submit this reply memorandum in further support of RRH's motion to dismiss Relator's Amended Complaint (the "Motion") (Dkt. 38).

INTRODUCTION

When dismissing Relator's first Complaint at the August 2024 bench hearing, the Court advised Relator of the specific deficiencies in the original Complaint. These included, among others, (1) Relator's failure to plead fraud with particularity under Rule 9(b) and *Chorches*, (2) her failure to identify a breach of the Vaccine Provider Agreement or a statutory violation regarding reporting adverse events from COVID-19 vaccines that was material to the government's payment decision, and (3) her failure to demonstrate protected activity in support of her retaliation claims. The Court granted Relator leave to file an Amended Complaint to overcome these issues, among others. But she has failed to do so, and the Amended Complaint should be dismissed with prejudice.

The Amended Complaint alleges no new factual allegations that adequately address the Court's previously identified pleading deficiencies. Relator's Response confirms as much, as it misrepresents RRH's arguments, avoids addressing the specific, narrow issues at play, doubles-down to repeat the same old allegations at a broad degree of generality, smuggles in new allegations not alleged in the Amended Complaint, and fails to explain how the Amended Complaint differs materially from the first Complaint. Because the Amended Complaint is, in all relevant respects, no different from the first Complaint, dismissal with prejudice is warranted.[1]

[1] Defendants reserve the right to further address Relator's arguments at the oral argument on the Motion, currently scheduled for March 11, 2025.

I. Relator Conflates RRH's Recommendation to Monitor Vaccine Recipients for Fifteen Minutes with a Legal Obligation to Report Adverse Events to VAERS.

From the very first sentence of the Response, Relator mischaracterizes RRH's position to assert that a vaccination provider's obligation to report to VAERS exists for only fifteen minutes after administering a COVID-19 vaccine. Dkt. 45, at 1; *see also id.* at 11. This mischaracterization not only distorts RRH's position but seeks to obfuscate the obligation to report to VAERS. As Relator's argument goes, if she can establish that RRH published guidance that VAERS reporting obligations exist for only fifteen minutes after the administration of a COVID-19 vaccine, Relator can then point to select adverse events that will never manifest within fifteen minutes (*i.e.*, a congenital birth defect) and therefore claim that RRH failed to fulfill its VAERS reporting obligations. *See* Dkt. 45, at 10–11.

Relator has conflated the recommended fifteen-minute *monitoring period* published in RRH's COVID-19 Vaccine Clinic Playbook with a vaccination provider's obligation under the Emergency Use Authorization conditions ("EUA Conditions") to *report* adverse events to VAERS following COVID-19 vaccination. *See* Dkt. 34-25, at 5 (separately stating a recommended fifteen-minute monitoring period and the requirement for vaccination providers to report to VAERS). RRH has not argued that a COVID-19 vaccination provider's obligation to report to VAERS exists only for a specific allotment of time. Instead, based on the terms of the Vaccination Provider Agreement and the EUA Conditions, RRH contends that the reporting obligation (1) belongs to the vaccination provider, and (2) must be geographically and temporally tied to the location where COVID-19 vaccines are handled. Dkt. 38, at 6–9. While the Vaccination Provider Agreement does not provide an exact window of time for reporting to VAERS, both the text and the context of the Agreement demonstrate, at the very least, that a reporting obligation does not travel with the vaccine recipient from the vaccination site to a separate episode of care at the hospital some

indeterminate time after vaccination. Because Relator has not alleged any facts with particularity regarding a RRH vaccination provider violating VAERS reporting obligations in geographical and temporal proximity to a RRH vaccine clinic, the Court can grant RRH's motion to dismiss without deciding if the VAERS adverse event reporting obligation is limited to a specific allotment of time.

II. Relator Cannot Satisfy *Chorches* Because She Does Not Allege Any Actions (Let Alone Fraudulent Conduct) Occurring at a Vaccine Clinic.

The obligations in the Vaccination Provider Agreement apply only to individuals involved in handling the COVID-19 vaccine. Relator has not (and indeed cannot) allege any actions that occurred at a RRH vaccine clinic. The reason is simple: she was never there and has no first-hand knowledge whatsoever regarding the administration of COVID-19 vaccines, any monitoring of vaccine recipients following vaccination, any adverse event reporting to VAERS by vaccination providers, or any other acts relating to the handling or administration of vaccines. Instead, the Amended Complaint attempts to manufacture Relator's personal knowledge of the administration of COVID-19 vaccines at RRH's vaccine clinics, but, in doing so, reveals that any knowledge Relator possesses about RRH's vaccine clinic locations and vaccine administration comes from her review of RRH's websites and press releases. *See* Dkt. 34 ¶¶ 42–43 n. 14–16 (citing websites visited on October 31, 2024 to support conclusory allegation that Conrad knew facts about RRH's vaccination locations and efforts). In other words, she has no first-hand, personal knowledge about what transpired in RRH's vaccine clinics during 2021 because, during this time, she worked at a UMMC hospital in Batavia as a physician assistant managing the care of hospital admissions. *Id.* ¶¶ 49–50.

Relator's experience in the hospital is not geographically and temporally connected to the handling of COVID-19 vaccines at a RRH vaccine clinic. Since the obligations from the Vaccination Provider Agreement are limited in this way, Relator cannot provide an insider's

account of suspected fraudulent activity that is supported by personal observations. Since the Amended Complaint does not provide details of the submission of any false claim, Relator must point to particularized, factual allegations, under *Chorches*, that create a strong inference that false claims were in fact submitted. *See United States ex rel. Pilat v. Amedisys, Inc.*, No. 17-CV-136 (JLS) (LGF), 2025 WL 436929, at *7 n.7 (W.D.N.Y. Feb. 7, 2025) ("Relators must rely on *Chorches* to plead their FCA violations because they do not allege the actual submission of false claims.").

The Second Circuit justified *Chorches*' alternative pleading approach because the facts of the case made clear that, without an alternative standard, the paradigmatic whistleblowers—*i.e.*, the line worker who witnesses the fraud firsthand or the accountant who processes the false claims—could, in certain circumstances, be foreclosed by the strictures of Rule 9(b) from asserting plausible theories of fraudulent schemes. *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 86 (2d Cir. 2017). Here, Relator is not blowing the whistle from the accounting department. Instead, the Amended Complaint tries—and fails—to allege a fraudulent scheme uncovered by a line worker. But in the healthcare services context, relators who have successfully alleged specific facts creating a strong inference that false claims were in fact submitted have typically been employees with first-hand observations of fraudulent activity connected to the reimbursable services that were the subject of the alleged fraud. *See, e.g.*, *United States ex rel. Pilat v. Amedisys, Inc.*, No. 23-566, 2024 WL 177990, at *3 (2d Cir. Jan. 17, 2024); *Chorches*, 865 F.3d at 83–84.

Simply put, Relator does not fit the mold of a paradigmatic whistleblower because there is no connection between her responsibilities as a bedside hospitalist in a hospital and the administration of COVID-19 vaccines at a RRH vaccine clinic. Moreover, she does not allege any

other facts that could create an inference that false claims were submitted, let alone the "strong inference" necessary to satisfy the *Chorches* alternative pleading standard. She never visited a vaccine clinic, and she alleges no facts connecting her VAERS compliance complaints to a fraudulent scheme motivated to submit false claims. Relator's Response points to paragraphs 96, 97, and 108 to argue she has sufficiently satisfied her pleading burden. Dkt. 45 at 23. But these allegations come nowhere close to satisfying *Chorches*' alternative pleading standard.

III. The Adverse Event Reporting Obligations Under the Vaccination Provider Agreement, the Vaccine Injury Act, and the EUA Conditions Do Not Extend to Relator's Alleged Theories.

Relator argues that the Vaccine Injury Act and EUA Statute (and corresponding EUA conditions) show "Congress and HHS do not limit reporting to Defendants [sic] definition of 'handling' a vaccine" and that "nothing in the EUA definition of 'vaccination provider' limits the scope of reporting obligations." Dkt. 45 at 10. These imprecise arguments blur discrete issues that RRH already cleanly briefed in its Motion but which will be clarified once again here.

First, as has been discussed before, the Vaccine Injury Act does not impose adverse event reporting obligations on a vaccination provider who administers COVID-19 vaccines. The Vaccine Injury Act imposes statutory vaccine reporting obligations only on "health care providers" and "vaccine manufacturers" with respect to vaccines listed on the Vaccine Injury Table. 42 U.S.C. §§ 300aa-25(b), 300aa-33(1). COVID-19 vaccines are not listed on the Vaccine Injury Table. 42 C.F.R. § 100.3. Thus, Relator cannot rely on the Vaccine Injury Act as a basis to assert an FCA claim premised on a false certification of compliance with this statute when the gist of Relator's theory involves only COVID-19 adverse event reporting, and this statute does not apply to COVID-19 vaccines.

Second, Relator seems to argue that while the contractual adverse event reporting obligations under the Vaccination Provider Agreement may be limited to those involved in

handling the vaccine, the statutory adverse event reporting obligations under the EUA Conditions are not similarly limited. Dkt. 45 at 10. But Relator fails to address meaningfully the language in the EUA Conditions. For starters, an entity must be enrolled in the CDC's Vaccination Program to be defined as a "vaccination provider." 86 Fed. Reg. 5200, 5204 n. 6; 86 Fed. Reg. 28608, 28621 n. 6. The EUA Conditions further state that "Vaccination providers . . . will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program." 86 Fed. Reg. 5200, 5208; 86 Fed. Reg. 28608, 28626. By defining "vaccination provider" with reference to the Vaccination Provider Agreement and requiring vaccination providers to follow the terms of that Agreement, the EUA Conditions support limiting the scope of the COVID-19 adverse event reporting obligation co-extensively with the contractual language in the Agreement.[2]

However, even assuming Relator was correct that the EUA Conditions were broader (which they are not) than the contractual terms under the Vaccination Provider Agreement, Relator does not explain how the EUA Conditions' statutory adverse event reporting obligations are broad enough to require adverse event reporting by hospital personnel, like Relator, who treated patients that received a COVID-19 vaccine some indeterminate time before their admission to the hospital (and in many cases did not receive a COVID-19 vaccine from a RRH vaccine clinic).

IV. Relator Cannot Establish Scienter Based on Diverging Medical Judgments About VAERS Reporting.

Relator cannot establish RRH acted with the requisite scienter to be liable under the FCA by pointing to a good faith disagreement regarding the requirement to report adverse events to

[2] As set forth in RRH's Motion, the adverse event reporting obligations under the EUA Conditions may be even narrower than the Vaccination Provider Agreement. Whereas the Vaccination Provider Agreement imposes adverse event reporting obligations on "individuals involved in *handling* the vaccine[,]" the EUA Conditions only obligate "Vaccinations providers *administering*" the vaccine to report select adverse events to VAERS. Dkt. 38, at 11-12.

VAERS. *Cf. United States ex rel. Kirk v. Schindler Elevator Corp.*, 130 F. Supp. 3d 866, 877 (S.D.N.Y. 2015) (citations omitted) ("Where there are legitimate grounds for disagreement over the scope of a . . . regulatory provision, and the claimant's actions are in good faith, the claimant cannot be said to have knowingly presented a false claim."). A provider's decision to report to VAERS requires the use of medical judgment. Whether an adverse event is reportable may depend on a medical professional's judgment about the surrounding circumstances. Under Relator's theory, if a vaccinated patient is killed in an automobile accident or hospitalized due to injuries from the accident, then a medical professional must report that patient to VAERS. Setting aside the fact that Relator's theory focuses on reporting obligations of hospital staff, not those temporally and geographically connected to the location where vaccines are handled, this theory leaves no room for a medical professional, using the diagnostic process, to rule out deaths or hospitalizations that have no obvious or even remote connection to the COVID-19 vaccine.

In this context, Relator's own allegations foreclose her ability to establish scienter insofar as Relator alleges that RRH leadership conducted an independent assessment of the patient files that Relator contended required VAERS reports and reached a different medical opinion on whether the patient's medical complaint required a VAERS report. Dkt. 38 at 25–26. The fact that Relator (who is not a physician) disagreed with RRH leadership (and her supervising physicians, the Finger Lakes vaccine hub, RRH's legal department, the New York Times, and apparently the CDC, HHS, FDA, DNV, and New York state officials) on this question does not allow her to convert RRH's good faith disagreement into a scheme to knowingly defraud the government.

V. Relator's Retaliation Claims.

Relator asserts several arguments with respect to her retaliation claims, all of which do not overcome the Amended Complaint's failure to adequately allege these claims. First, Relator contends the Amended Complaint adequately alleges the protected activity element even if her

complaints to RRH leadership did not mention "fraud." Dkt. 45, at 28. She contends that raising concerns with legal compliance was enough. *Id.* at 32. But the FCA is not a "vehicle for punishing garden-variety breaches of contract or regulatory violations." *Univ. Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016). Therefore, merely notifying RRH leadership of legal compliance concerns absent additional allegations connecting the asserted noncompliance to the fraud scheme fails to demonstrate protected activity for an FCA retaliation claim. *Pilat* underscores this. There, the Second Circuit determined the whistleblowers, Pilat and Maniscalco, satisfactorily alleged protected activity because, although their complaints to management identified issues with patient care, their third amended complaint "also explains how those acts are fraudulent[.]" *United States ex rel. Pilat v. Amedisys, Inc.*, No. 23-566, 2024 WL 177990, at *2 (2d Cir. Jan. 17, 2024).[3] Here, the Amended Complaint provides no plausible connection between a hospital's alleged failure to report adverse events observed in hospital patients and alleged fraudulent practices arising from a RRH vaccine clinic. This is simply a contrived theory under which liability cannot be established under the Vaccination Provider Agreement or the EUA Conditions; and for this reason, there is no surprise that the Amended Complaint fails to explain how "a reasonable

[3] Relator's other cited cases are in accord. In *Bernstein*, the Court observed that the relator's complaint alleged both that "she expressed concern to her supervisors about Dr. Silverman's practices" and paired those allegations with others to explain how those practices "were fraudulent." *Bernstein v. Silverman*, No. 5:20-CV-630 (MAD/CFH), 2024 WL 3595626, at *26 (N.D.N.Y. July 31, 2024). Similarly, in *Applied Memetic*, the Court found the complaint alleged protected activity in support of an FCA retaliation claim even where the relator did not use the language of "fraud" to express her complaints because "she was raising concerns about fraud nonetheless." *United States ex. rel. DaPolito v. Applied Memetics, LLC*, No. 5:21-cv-270, 2024 WL 5316335, at *21 (D. Vt. Dec. 4, 2024). While the Court in *Northern Adult* held protected activity was sufficiently alleged based merely on complaints of regulatory violations, *United States v. Northern Adult Daily Health Care Ctr.*, 205 F. Supp. 3d 276, 299–300 (E.D.N.Y. 2016), this case preceded *Pilat*, wherein the Second Circuit indicated that complaints not sounding in fraud (*i.e.* patient care) could demonstrate protected activity if other allegations linked those complaints back up to a fraud scheme.

employee in the same or similar circumstances might believe that the employer is committing fraud against the government." *Conte v. Kingston NH Operations, LLC*, 585 F. Supp. 3d 218, 243 (N.D.N.Y. 2022) (citations omitted) (dismissing FCA retaliation claim where relator's complaint lacked factual allegations as to the objective element of alleging protected activity).

Second, Relator contends she has adequately alleged a causal connection between her termination and complaints of VAERS non-compliance. Dkt. 45, at 33–36. She alleges that the temporal proximity between her alleged termination and her complaints to RRH leadership in the months before raises the inference, at the motion to dismiss stage, that her complaints were a but-for cause of her termination (regardless if other plausible causes exist too). *Id.* at 33–34. However, Relator fails to appreciate that an "intervening event between the protected activity and the adverse employment action may defeat the inference of causation where temporal proximity might otherwise suffice to raise the inference." *Joseph v. Marco Polo Network, Inc.*, No. 09 Civ. 1597 (DLC), 2010 WL 4513298, at *18 (S.D.N.Y. Nov. 10, 2010). Even without considering Relator's *Serafin* affidavit,[4] Relator's intended refusal to be vaccinated by the deadline as required by the New York vaccine mandate was the intervening cause of her termination. The Amended Complaint shows that between March 2021 and September 2021, Relator notified RRH leadership of her divergent understanding of VAERS compliance. *See generally* Dkt. 34, ¶¶ 57–89. On September 26, the New York Times published an article in which Relator "mentioned concern about vaccine side effects *as the reason she did not want to get vaccinated*." *Id.* ¶ 89 (emphasis

[4] The Court can avoid striking Exhibit D to the Peacock Declaration or converting the Motion to a Rule 56 motion by simply taking judicial notice of the fact of the *Serafin* litigation and that filings made therein contained certain information, without regard for the truth of the matters asserted. *See Kramer v. Time Warner, Inc.*, 937 F.2d 767, 774 (2d Cir. 1991) (holding district court did not err in judicially noticing publicly-filed documents with the SEC in adjudicating motion to dismiss and observing that the "practice of taking judicial notice of public documents is not new").

added). On October 6, 2021—the day before the October 7 deadline by which healthcare workers must be "fully vaccinated"[5]—Relator met with RRH's HR department to discuss the New York Times article and her "test-to-stay" concerns. *Id.* ¶ 90. The sequence of these events demonstrates that Relator's refusal to comply with state regulations intervened to extinguish an inference of a causal connection raised by any temporal proximity between her complaints and termination.[6] Moreover, as shown by the New York Times article, Relator's intended refusal to receive the COVID-19 vaccine on the eve of the compliance deadline is an obvious, alternative explanation for her termination. *Pilat*, 2025 WL 436929, at *4 (explaining that the plausibility standard depends on several considerations, including "the existence of alternative explanations so obvious that they render [the] plaintiff's inferences unreasonable"); *cf. Powell v. Merrick Academy Charter School*, No. 16-CV-5315 (NGG) (RLM), 2018 WL 1135551, at *10 (E.D.N.Y. Feb. 28, 2018) (dismissing Title VII retaliation claim where complaint's allegations provided an obvious, alternative explanation for employee's termination that defeated any inference of causation potentially raised by temporal proximity of protected activity and termination).

5 10 N.Y. CODE, RULES, & REGS. 2.61(c).

6 RRH's causal connection argument applies equally to Relator's FCA retaliation claim and state law retaliation claims since those claims all require proof of a causal connection.

Dated: February 21, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on all parties that have appeared through the Court's electronic filing system on February 21, 2025.

/s/ David W. Klaudt
David W. Klaudt